CONSULTATIONS AND WORKSHOPS

The Interaction between Assessors and Managers of Microbiological Hazards in Food

Report of a WHO Expert Consultation
Kiel, Germany
21-23 March 2000

Federal Ministry for Health Germany

Issued by the World Health Organization
In collaboration with
The Food and Agriculture Organization of the United Nations and
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FOOD SAFETY PROGRAMME
WORLD HEALTH ORGANIZATION

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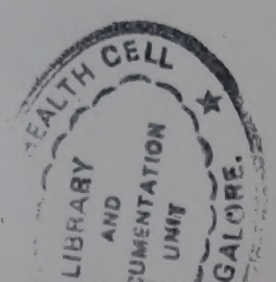
World Health Organization
Food Safety Programme
CH-1211 Geneva 27
Switzerland

Email: foodsafety@who.int
Fax: +41 22 791 48 07



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A WHO Expert Consultation on the Interaction between Assessors and Managers of Microbiological Hazards in Foods, was held in collaboration with the Federal Government of Germany, the Institute for Hygiene and Food Safety of the Federal Dairy Research Center and the Food and Agriculture Organization of the United Nations. The Consultation was sponsored by the Federal Government of Germany and hosted by the Institute for Hygiene and Food Safety of the Federal Dairy Research Center in Kiel, Germany from 21-23 March 2000. Dr Hans Böhm, Federal Ministry for Health of Germany, opened the Consultation and welcomed the participants on behalf of the Federal Minister for Health, Mrs. Andrea Fischer and the Federal Minister of Food, Agriculture and Forestry, Mr Karl-Heinz Funke. The background papers for this consultation (Annex 1) and the complete list of participants (Annex 2) are attached.

In welcoming the participants, Dr Böhm expressed his appreciation to the experts for coming to Kiel to discuss the interaction between risk assessors and risk managers and to formulate recommendations. Dr Böhm noted that in the future, risk would be estimated with more accuracy and that measures for the reduction of risk would be evaluated prior to the introduction of new regulations.

The Consultation elected Professor Jean-Louis Jouve as Chairman and Dr Anna Lammerding was appointed as Rapporteur. In his opening remarks Professor Jouve pointed out that the main goal of the consultation was to provide guidance on effective interaction between risk assessors and risk managers. This guidance should address activities in the risk assessment of microbiological hazards in food. It is particularly relevant to the Codex Alimentarius Commission (CAC), its subsidiary committees and advisory expert bodies, as well as to microbiological risk managers and risk assessors at the national level. Professor Jouve urged participants to use the general risk management framework for food safety in the report of the Joint FAO/WHO Expert Consultation on Risk Management and Food Safety held in 1997 as a basis for their discussions. He requested the participants to address in greater detail the interactions required between risk assessors, risk managers, and where appropriate other stakeholders in order to maximize the relevance and utility of risk assessments.

Professor Jouve pointed out that independence, transparency, and robustness of the scientific analyses and advice are essential determinants of their credibility. Nonetheless, effective dialogue among risk assessors, risk managers, and other stakeholders is essential to maximize the utility of the assessment findings and to ensure that both scientific and societal goals are met. In particular, the risk managers can ensure that the risk assessment considers and provides all scientific information necessary for making policy decisions. The risk assessors can ensure that the appropriate scientific concerns are addressed. In addition to risk managers, other stakeholders can provide insight into the resources necessary to generate data for the assessment, the scale of the problem and the values at stake. All these perspectives are necessary to ensure the appropriate use of resources and to produce scientifically sound risk assessments that are relevant to risk management decisions and public concerns.

There is increasing recognition of the need for risk-based sanitary measures at both the international and national level. The Sanitary and Phytosanitary (SPS) provisions of the World Trade Agreement encourage "harmonization" of standards for food safety: "To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or

phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for …" (2). Further, the dispute settlement system has recently shown on several occasions that the rules imposed on Members can be effectively enforced. In support of the SPS Agreement, the CAC now has a comprehensive action plan to incorporate risk analysis in its activities wherever appropriate (1).

The General Agreement on Tariffs and Trade (GATT) decision on sanitary and phytosanitary measures (SPS) reaffirms that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health. Members also desire to improve human health, animal health, and the phytosanitary situation. In addition, Members agree that: "contracting parties shall ensure that their SPS measures are based on an assessment, as appropriate to the circumstances, of the risk to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations" (2).

1. BACKGROUND

The World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations have been in the forefront of the development of risk based approaches for the management of public health risks for hazards in food. Risk analysis is well established for chemical hazards. Now, WHO and FAO are extending the experience and expertise developed from risk analysis of chemical hazards to that of microbiological hazards.

A foundation for microbiological risk assessment was established through a series of consultations held by FAO and WHO and through the documents developed by the Codex Alimentarius Commission. The Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues held in 1995 was the first in this series (3). It defined risk analysis as a process composed of three components:

- **Risk assessment** – a process of systematic and objective evaluation of all available information pertaining to foodborne hazards.
- **Risk management** – the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.
- **Risk communication** – the interactive exchange of information and opinions concerning risks and risk management among risk assessors, risk managers, consumers, and other interested parties.

In 1997 a Joint FAO/WHO Expert Consultation on Risk Management and Food Safety identified a risk management framework and the elements and general principles of food safety and risk management. It describes risk management as a continuing process of evaluation, option assessment, implementation, and monitoring & review (4). The Joint FAO/WHO Expert Consultation on the Application of Risk Communication to Food Standards and Safety Matters was held in 1998 and it identified elements and guiding principles of risk communication and strategies for effective risk communication (5). Risk Assessment is defined in the Codex "Principles and Guidelines for the Conduct of Microbiological Risk Assessment" (6) as a scientifically based process

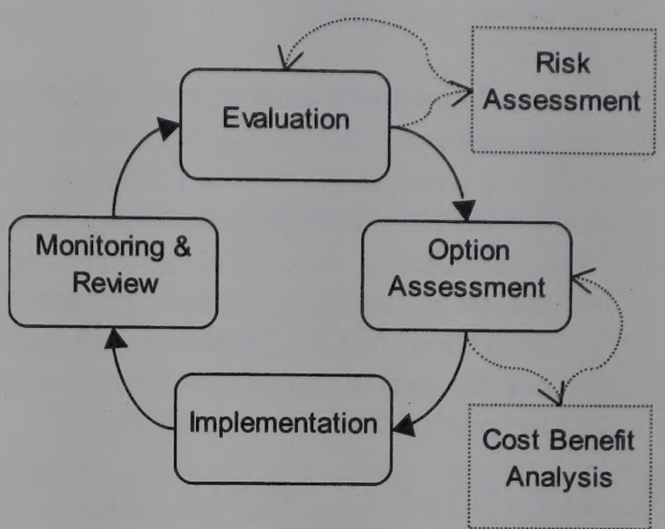
consisting of the following steps: i) hazard identification, ii) hazard characterization, iii) exposure assessment, and iv) risk characterization.

This document is intended to build upon the foundation for risk analysis and risk assessment established by the joint FAO and WHO Consultation Reports and the documents produced by the Codex Alimentarius Commission.

2. INTRODUCTION

This report is a further elaboration of the risk analysis process. The interaction of risk managers and risk assessors is considered in detail. The diagram (Fig. 1) highlights two points in the risk management cycle where interaction with risk assessors occurs. However, interaction may be necessary at other places as well. Risk assessment and cost benefit analysis are independent; science based activities conducted to provide the basis for risk management decisions. Risk assessment and risk management activities are typically not linear processes but iterative and fluid. Frequently, the risk management goals and the risk assessment activities will be revised and refined based on the scientific findings as the work progresses.

Fig. 1 Risk Management Framework



2.1. Scope

This document is directed to risk managers and risk assessors at a national or international level. Risk managers, in an international context, are the members of the Codex Alimentarius Commission, and of its subsidiary committees. In a national context, public authorities and national policy makers make and implement decisions and are, therefore, risk managers. Other parties may be involved in managing the risk (i.e. operational risk managers, such as inspection personnel) however, their roles are not considered in this document. In some cases, the appropriate risk manager or decision-maker may not be recognized at the start of the assessment.

The following discussions and recommendations pertain to situations that allow some deliberation and due process. These recommendations would not be sufficient during emergency response management actions. The nature of risk management and risk assessment interactions may differ between the international and the national level.

Structured risk assessment and risk management processes should help decision makers develop effective solutions for the reduction of foodborne illness. The public should be involved in the risk management decision making processes. These processes should not be construed as prescriptive and should allow flexibility. It is most important that the decisions made and actions taken are rational, defensible, and arrived at in an open and transparent manner. It may not be necessary to spend extensive time on each task, particularly if a management issue is well

characterized. However, risk managers may wish to address each step for purposes of clarification, context, transparency, better understanding of exactly what the problem is, and what the goals are (why is a risk assessment necessary, and what will the outcome be?).

2.2. Objectives

The objectives of the Consultation were to provide guidance on:

- effective linkage between risk assessment and risk management and to define in greater detail the interactions required between risk assessors and risk managers during the conduct of risk assessment.
- development of a clear and comprehensive description of the scope of work for risk assessment.
- the translation of risk assessment results into intervention strategies.
- the use of measures, indices, and parameters (e.g. Acceptable Risk, Appropriate Level Of Protection (ALOP), Disability Adjusted Life Years (DALY), Food Safety Objectives (FSO), and Targets) in communications between assessors and managers of microbiological hazards in food in international trade.

3. FUNCTIONAL SEPARATION OF RISK ASSESSMENT AND RISK MANAGEMENT

The draft Working Principles for Risk Analysis (7) and the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (6) refer to the functional separation of Risk Assessment and Risk Management. Individual(s) who prepare the risk assessment should not normally be the same individual(s) who are responsible for the management of the risk. The tasks of risk assessment and risk management are best performed by different people or functional groups. However, it is recognized that in many countries an individual may act as both a risk manager and an assessor. In all cases it is paramount that the activities of the risk analysis process are transparent and appropriately documented. This applies to all interactions between risk assessors and risk managers, or to the separation of the activities by an individual.

Functional separation is essential to the conduct of risk analysis activities in order to maintain the scientific integrity of the risk assessment process and to avoid political pressures that would undermine the objectivity and the credibility of the conclusions. Separation of risk management and risk assessment helps to ensure that assessments are not biased by pre-conceived opinions related to management solutions. However, there is a need for frequent interaction between risk managers and risk assessors in order to arrive at effective risk management decisions. Active interaction is necessary to ensure that the assessment will meet the needs and answer the concerns of the risk manager. The assessors must understand the manager's questions and both parties must acknowledge any constraints, which may impact on the risk assessment. The strengths and limitations of the assessment must be properly communicated so that people using the risk

assessments can properly understand the results. Interactions between assessors and managers do not end with the completion of the risk assessment. There will often be exchanges of information and input from assessors during subsequent risk management activities, for example, during the option assessment stage and in communication of results to interested parties.

The nature of the interaction between risk assessors and risk managers may differ according to the way national or international organizations are structured. For example, organizational as well as functional separation between risk managers and risk assessors is currently envisaged in the Codex system for microbiological food safety. Nevertheless, interaction and communication are essential for effective risk management while maintaining the scientific integrity of risk assessment, and should include active steps such as open review.

There are constraints, and inefficiencies in the risk management procedures as carried out by the Codex Committee on Food Hygiene, and improved interaction between risk assessors and risk managers is needed. With this in mind, it is suggested that FAO and WHO give strong consideration on how experts in risk management procedures can feed into the work of the ad hoc FAO/WHO risk assessment consultations, while at all times clearly maintaining risk assessment and risk management as separate functions.

4. TRANSPARENCY

Transparency is a key objective of the risk analysis approach and its importance cannot be over emphasized. This is reflected in the Codex Statement of Principles relating to Food Safety Risk Assessment (8), the Codex Committee on Food Hygiene (CCFH) Guidelines for Microbiological Risk Assessment (6), and the CCFH draft Guidelines for Microbiological Risk Management (9). Transparency in risk assessment means that all assumptions, data, inferences, and conclusions are explicitly documented and made available for open review and discussion. Transparency in risk management means that the process is open and available for scrutiny by interested parties including stakeholders and consumers who may be affected by the outcome of the risk analysis and risk management activity (4).

Risk assessment and risk management interactions may be subject to time constraints, especially in situations where a food safety problem requires rapid deployment of interim or emergency measures. Effective risk management in emergency situations depends on an urgent dialogue between assessors and managers. However, even in such situations managers should strive for open communications in order that the need for transparency is satisfied to the greatest possible extent.

Legal and proprietary constraints regarding the release of data may exist at the national and international levels. Data handling can be a sensitive issue. For example, industry sources may prefer to withhold data that would be valuable for risk assessment if they believe that confidentiality cannot be assured. Although there should be a general thrust towards data release, especially in the international context, certain data used in a Risk Assessment may need safeguarding to preserve confidentiality. In addition, the provisions of national data protection legislation may have a bearing on disclosure of information. In order to ensure that data made available by stakeholders is reliable and representative, it may be appropriate for an independent expert body to review and evaluate the

information. In all situations risk managers and risk assessors should work together to ensure that transparency in the use of data is maximized.

Conflict of interest can potentially contribute to bias and loss of transparency. Conflict of interest arises from a wide spectrum of actions involving personal gain or political or economic interest. It is essential that the biases of risk assessment experts and participation by interested parties do not compromise the process. Measures may be needed to ensure that risk assessments are made in an independent and transparent atmosphere. Experts should declare any interests that could constitute a real, potential, or apparent conflict of interest in order to assure the technical integrity and impartiality of the conclusions reached in the assessment. This disclosure would include any relationship with a specific stakeholder in the issue under consideration. Risk managers will decide if the declared interest could affect the participation of the experts in specific aspects of the process.
Interactions with stakeholders

Risk managers are responsible for ensuring that stakeholders are involved in risk analysis, and that their views are taken into account at all relevant stages of the risk management process. Stakeholders are interested parties who may be affected by the outcome of the risk management activity. Effective two-way communication between risk experts, risk managers, and the affected segments of industry and the public is both an essential part of risk management and a key to achieving transparency (5). Risk managers should consider how to optimize stakeholder participation at each stage of the risk management process, including involvement in the interactions with risk assessors.

Various avenues exist for stakeholder participation. The approach selected should be appropriate to the circumstances and the stage of the risk management process. Different fora will be more or less appropriate depending on the purpose of the stakeholder involvement. For example, interested parties may contribute to issue identification and characterization, provide data and other inputs for risk assessment, provide alternatives for options assessment, participate in discussion to arrive at consensus, or voice public concern. Where stakeholders are not directly involved in risk assessor/risk manager interactions, risk managers need to bear in mind the importance of on-going communication in the interest of transparency. Finally, interaction among risk assessors, risk managers and stakeholders is necessary to effectively communicate a risk management decision.

Formal systems are in place at the international level for stakeholder involvement. To preserve the integrity of these interactions, risk managers should ensure that individual participants are appropriate representatives of the stakeholder group. It should be the responsibility of individual countries to involve national stakeholders in discussion at the country level, and to ensure that their input is appropriately represented in international discussions.

5. RISK EVALUATION

Risk evaluation is the initial stage of risk management activities. It encompasses several steps including: i) identification of a food safety problem, ii) establishment of a risk profile, iii) ranking of the hazard for risk assessment and risk management priority, iv) establishment of risk assessment policy, v) commissioning of risk assessment, and terminates, following risk assessment, with vi) consideration of risk assessment results (4).

At the outset of a microbiological risk management activity, the managers and assessors should be clearly identified. The particular situation and the problem context will determine who are the risk managers. In the Codex Alimentarius context, the managers are the members of the Codex Alimentarius Commission, and of its subsidiary committees. In a national context, public authorities and national policy makers usually make, and implement, decisions.

It is important to involve risk assessment expertise in the early stages of the process. Interaction between managers and assessors is useful to clarify the problem or issue, identify risk management goals, and make initial decisions on the scope, range and relevant policies that will guide a subsequent risk assessment.

5.1. Identification of a food safety problem

Initial identification of food safety problems and issues is a risk management function. Relevant information will often arise from various sources e.g. regulators, public health institutions, the food industry, science providers, and interested consumer groups. This initial risk management function is usually carried out in conjunction with risk assessors. The information leading to the identification of a food safety problem may be provided by a single stakeholder or may be the result of collaboration among many stakeholders.

A food-borne microbiological public health problem may be well recognized or unknown. It may be a new or latent problem. A problem may be identified from information on the presence, prevalence and/or concentration of hazards in the food chain and in the environment. Disease surveillance and monitoring information, epidemiological studies, clinical studies, laboratory studies, changes in production practices (including process innovation), lack of compliance with standards, expert opinion and public perceptions and concerns may also signal a problem. In some cases, lack of information may trigger a requirement to obtain more information on food-borne risks to human health. In other cases, the need for a new risk management approach may arise from a problem in trade. It is important to note that information associated with a particular food safety issue may arise from a wide range of sources at both the national and international levels.

If the problem or issue warrants further evaluation, the next step will be to assemble a risk profile. The urgency with which the work should be done, and who will be involved in compiling the risk profile, are the risk manager's responsibility.

5.2. Establishment of a risk profile

Elaboration of a risk profile is essential for effective risk management. A risk profile should place an issue within a food safety context. Also it should provide as much information as possible to guide further action. Establishment of a risk profile will help to clarify risk management questions and goals. The nature of the food safety issue will define the amount of detail included in the risk profile. The risk profile may be developed in respect of foods in domestic or international trade. In many respects, the risk profile will flow from information sources used to initially identify a food safety issue. It is critical that the risk manager involves risk assessors and other scientific specialists

who have detailed knowledge of food safety issues when establishing a risk profile. Other representation will be included as appropriate.

A risk profile may include the following features:

- Administrative information, including initial description/statement of the issue
- Description of the commodity (may include distribution, marketplace), disease agent, outcome of exposure; food safety scenario (i.e. particular processing, handling, consumption profile)
- Values potentially at risk (human health, may in some situations include economic values, cultural, aesthetic)
- Distribution of risk, i.e. who are the producers of the risk, who benefits from the risk situation, who bears the risk.
- What characteristics of the commodity/agent might affect risk management options?
- What are known risk management characteristics of the risk producer and of the risk bearer?
- What are the current risk management practices relevant to the issue?
- What are the public perceptions of the risk?
- Familiarity and substantial equivalence
- International agreements, if any, that affect the risk issue.

A microbiological risk profile might include reference to: prevalence and concentration data on the hazard at all points in the food chain (including imported food), inputs to the food chain that impact on hazard levels, monitoring and surveillance data from the exposed human population, consumer values and perceptions of risk, and potential consequences of any risk management options that might be taken. As risk profiling may strongly influence further risk management activities, appropriate communication between all stakeholders must be maintained at all times.

The risk profile should be documented in such a way that it can be used by risk managers to prioritize a food safety issue in relation to other issues. This will help to facilitate a decision on further actions. Prioritization will often involve appropriate consultation with a range of stakeholder groups, either on an informal or formal basis.

The primary goal of risk managers is to protect and improve public health, and all stakeholder groups that are involved with a food safety issue should understand this. Other goals such as ensuring fair practices in international trade may be identified in particular circumstances. Risk management goals should be explicit in order to avoid misunderstanding of the outcomes desired.

Establishing risk management goals will require extensive interaction with all stakeholders that are party to the particular food safety issue, and it is likely that risk assessors will provide valuable insight to this process.

After articulation of risk management goals, it may be decided that a risk assessment is necessary. Other actions may also be chosen e.g. immediate imposition of hygiene measures to negate a potentially serious food safety problem. In some cases, the problem will be judged insignificant on the basis of the risk profile, and no risk management measures will be taken.

5.3. Ranking of the food safety issue for risk management priority

Ranking of the particular food safety issue for risk management priority is essentially a role for risk managers, together with stakeholders. However, interaction with risk assessors on technical aspects of the issues to be addressed by risk managers may facilitate a ranking process.

5.4. Establishment of risk assessment policy for conduct of risk assessment.

Establishment of microbiological risk assessment policy for the conduct of risk assessment is specifically identified as a risk management responsibility (6). It serves to protect the essential scientific independence and integrity of the microbiological risk assessment, and should be carried out in full collaboration between risk managers and risk assessors and other stakeholders.

Typically, microbiological risk assessment policy should address transparency and freedom from bias in the risk assessment process as well as clarity and consistency in the outputs of the risk assessment. Risk assessment policy should determine the essential elements covered by risk characterization, the questions to be addressed by risk assessment and provide documented guidelines for dealing with uncertainties (e.g. application of safety factors). Risk management policy should provide guidance for value judgements or policy choices, and make provisions for apportionment of adequate resources, and for peer review. The rationale for all judgements that are part of risk assessment policy should be clearly documented for inclusion in the final risk assessment report.

Risk assessors should focus on science-based evidence and analysis. It is important that they understand that the purpose of their work is to help the risk manager make an informed decision. Establishing the scope, range and policy of a risk assessment are interactive processes that require considerable consultation and interchange between risk managers, risk assessors, and stakeholder groups. This interaction is likely to be ongoing as the risk assessment develops.

The scope of the risk assessment is dependent on the reason for doing the assessment and the risk management goals that were identified. Traditionally, risk assessment has been viewed simply as the means to provide an estimate of risk. However, it can serve much broader applications such as estimating the relative value of different hygiene interventions in reducing risks to consumers. The scope of the risk assessment will define the parts of the food chain considered, and will provide the necessary focus for the scientific work involved in risk assessment.

It is anticipated that risk assessment policy may be further refined during the risk assessment process, as a result of continued interaction between risk managers and risk assessors. During the development of the risk assessment itself it may be necessary to re-orient the scope of the risk assessment, clarify particular objectives, and anticipate additional points where policy decisions are needed.

Risk assessment may be subject to practical constraints that have to be clearly identified and communicated to all stakeholder groups before risk assessment begins. Such constraints include time, resources, expertise, and data, and must be described in the final document (especially if they influence the outcome of risk characterization). Risk assessors and risk managers together must

ensure that the boundaries that are established do not compromise resolution of the risk management questions that are asked e.g. spatial or temporal issues (data from where, and when); representation of variables (e.g. gender, time, space); and dimensions of uncertainties (sampling errors, measurement errors).

5.5. Commissioning the risk assessment

The risk manager is responsible for establishing the risk assessment team and ensuring that the outcomes of all previous stages in the risk evaluation process have been adequately communicated to that team.

The qualifications and credibility of assessors must be considered, and a multidisciplinary, team approach is ideal. Scientific specialists may include microbiologists, health professionals, veterinarians, food scientists, statisticians, and epidemiologists. Part-time inputs from consultant specialists may also be required.

The risk assessment team should prepare a project plan, and provide an assurance to the risk manager that the risk management questions that have been presented can be adequately answered. This may involve negotiation between risk managers and risk assessors, and re-examination of the scope, range and policy of the risk assessment. Risk assessors should also identify their likely data needs at this stage.

Biases may be introduced by the risk assessor, or by a misrepresentation of the system under examination. In this respect, model validation can be difficult, and costly. However, risk assessors should try to ensure that the models are indeed faithful representations of the reality they are attempting to model. Thus, a review process should be established, with external independent reviewers to ensure risk assessment validation. The review process should involve experts who can assess the technical aspects of the work, and also, experts who understand the food system and human health components of the issue under investigation.

Risk assessors must communicate risk estimates in a manner that can be properly utilised for evaluating different risk management options. The presentation of the final results of the risk assessment should be tailored as appropriate for different audiences.

5.6. Consideration of risk assessment results

Risk assessors must communicate the outcomes of the assessment appropriately. Entirely different types of reports are needed for scientific and non-scientific audiences. Scientists generally want more detail than non-scientists do. Risk managers may need more detail than the public. Reports for the scientific community will be very detailed, whereas descriptive, less detailed summary presentations and key statistics with their uncertainty intervals are generally more appropriate for non-scientists. To handle the different levels of sophistication and detail needed for different audiences, it may be useful to design a presentation in a tiered format where the level of detail increases with each successive tier.

In general, probabilistic analyses are difficult to understand. Considerable effort should be made by the assessors to clearly translate the assumptions, uncertainties and outcomes in a manner that is understood by risk managers and other stakeholders. It may be useful to establish principles for communicating these aspects so that they may be properly dealt with in the risk management phase.

As more risk assessments are performed, there may be a tendency to reduce rather than expand on the information provided in the document. It may be appropriate to establish a format or information framework for risk assessment so that all assumptions, references, etc., used in defining a specific parameter are clearly outlined in or attached to the risk assessment.

Risk assessors must be aware of the importance of communicating insights gained during literature review, model building and analysis. It is important for risk managers to understand several aspects of risk assessment in order to make appropriate option assessments. These include: the degree of variability and uncertainty, and the confidence that the risk assessors have in the risk estimate; the key sources of variability and uncertainty and their impacts on the analysis; the critical assumptions and their importance to the estimate; the unimportant assumptions and why they are unimportant; and the extent to which alternative, plausible assumptions or models could affect any conclusion. Risk managers should be made aware of key controversies concerning the data or assumptions used. While not impinging on risk management responsibilities, the risk assessor should discuss how risk models might be used in evaluating options.

In the risk evaluation step risk managers determine whether the current level of risk, as determined through risk assessment, is acceptable. In other words, is the risk of enough concern to warrant measures for reduction? If the risk is acceptable no further action is required. If the risk is unacceptable managers need to consider appropriate interventions. An additional complication in the management of microbiological risk is the lack of a common understanding of the process risk managers should use to evaluate risk. Zero risk is not achievable because it is generally assumed that a single pathogen has some probability of causing illness under certain circumstances. Also, illness from microorganisms in food is not a new risk that we can choose to accept or reject, but a risk we have always experienced, although perhaps not at the current level. For these reasons microbiological risk evaluation requires a more sophisticated approach than simply determining an acceptable level of risk. Some countries have set risk reduction goals with associated time frames in recognition of this difficulty (11).

Many terms and concepts are currently used to describe the decision process of risk managers in the risk evaluation step. These terms include appropriate level of sanitary or phytosanitary protection (ALOP), Tolerable Level of Risk (TLR), Food Safety Objectives (FSOs), and As Low As Reasonably Achievable (ALARA).

The SPS Agreement of the World Trade Organization refers to the appropriate level of sanitary or phytosanitary protection (ALOP). ALOP is defined in the agreement as the level of protection deemed appropriate by the Member establishing a sanitary of phytosanitary measure to protect human, animal or plant life or health within its territory (2). This approach recognizes that there will be differences between countries but assumes there will be agreement within a country

on the ALOP. It also assumes that there is a single level (a bright line) above which the risk is unacceptable and below which the risk is acceptable.

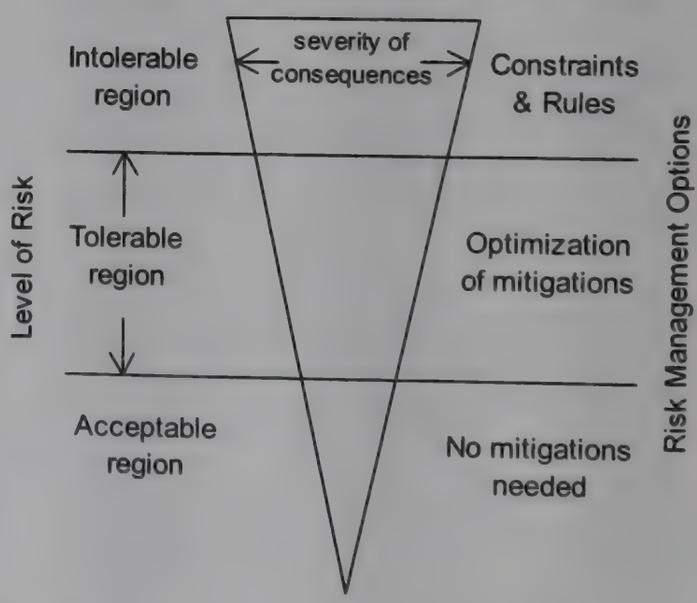
The *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management* under development in the Codex Committee on Food Hygiene refers to tolerable risk which is determined primarily by human health considerations (9). This approach also assumes a bright line level of tolerable risk.

Food Safety Objectives (FSOs) is a term used in some Codex documents, although at the time of this consultation the definition of the term remained to be agreed in the Codex. The International Commission on Microbiological Specifications for Food defines FSOs as a statement of the frequency or maximum concentration of a microbiological hazard in a food considered acceptable for consumer protection. The concept of FSOs links management approaches with acceptability considerations. FSOs convert public health goals into objectives or aims that can be addressed by food industries, producers, processors and marketers. FSOs will typically be expressed as a maximum concentration or probability of occurrence of a pathogen, toxin, or metabolite in food. The availability of quantitative information on risks allows the identification of an FSO. FSOs may provide a tool for the design and validation of food control systems, elaboration of food standards, and determining the equivalence of sanitary measures (10).

Establishing an FSO allows industries to use different technologies to achieve the same level of consumer protection. The development and use of FSOs is consistent with the concepts of WTO and its SPS agreement and provides a framework for harmonization of microbiological and other acceptance criteria for foods in international trade, in the same manner as the maximum residues levels and other chemical criteria (9).

ALARA or As Low As Reasonably Achievable is also a concept which links risk management approaches with acceptability considerations (Fig. 2). Both the level of risk and the severity of cases are used to categorize risk into intolerable, tolerable or acceptable regions. In the intolerable region the risk is unacceptable. The measures for risk reduction available in this region generally involve bans on products or other regulatory measures. The acceptable region is a level of no concern and risk reduction measures are not needed. The tolerable region is a range where risks are acceptable or not, depending on the adequacy of risk reduction interventions. Within the tolerable region there is usually a wider range of options available than in either the acceptable or intolerable regions. The challenge for risk management is selecting the optimal set of interventions to reduce the risk as low as reasonably achievable (ALARA) (12).

Fig. 2 ALARA
As Low As Reasonably Achievable



Currently a wide range of terms are used in the literature on risk management; including Codex. Interaction between assessors could be improved through the use of a single term (e.g. ALARA, ALOP, TLR, and FSOs) in communications between assessors and managers. However, experience in the management of foodborne risk has shown that the establishment of a bright line level for acceptable risk is extremely subjective and quite specific to the context of the situation. ALARA (As Low as Reasonably Achievable) divides risk into three regions in contrast to the bright line approach. This may be preferable in the management of food safety risks.

6. RISK MANAGEMENT OPTION ASSESSMENT

6.1. Identification of available management options

If the risk estimate is judged to reflect a negligible risk to consumers, given current food safety goals, the risk managers will likely choose to maintain the status quo. If managers choose to accept existing sanitary measures and not consider additional measures, no interaction with risk assessors would be envisaged.

The primary responsibility for compiling the list of available options lies with the risk manager in consultation with other stakeholders e.g. industry, consumers, regulatory food scientists, academia, etc. However, experience gained by the risk assessor may be useful in compiling the list of options and therefore the managers and assessors may interact on this basis. The risk assessors should provide good explanatory narrative in support of risk estimates generated from the risk assessment process to assist in compiling a list of options.

The primary objective of microbiological risk management option assessment is optimization of the interventions necessary to prevent and control microbiological risks. It is aimed at selecting the option or options that achieve the chosen level of public health protection for the microbiological hazard in the commodity of concern in as cost effective manner as possible within the technical feasibility of the industry. There are no hard and fast rules about how managers select options but there are a number of possibilities based on the food safety issue at hand, and the choice of a risk management approach (4).

The interaction between managers and assessors depends on the scope of the risk assessment. Often the risk assessment is designed to identify the stage in the food chain where interventions will most effectively reduce the public health burden attributable to the specific food and pathogen in question. A risk assessment may also be initiated to examine the cost effectiveness of current controls or to evaluate a new technology for control. In this case a list of options for consideration will be included in the scope. In an emergency situation with an emerging pathogen where the etiology of disease is not well understood the options comparison will be abbreviated.

6.2. Selection of the preferred management option.

Selection of a preferred risk management option will primarily involve a systematic evaluation of the likely impact of different sanitary measures on reducing or eliminating risk to human health. One of the key interactions between the risk managers and risk assessors is evaluating the likely efficacy of potential mitigation strategies. The risk assessors can provide valuable insights into the steps in the production, processing, and marketing of a food that are most likely to lead to the desired level of control of a foodborne disease. This includes measures such as mitigation elasticities that can provide estimates of how the extent of control at a particular point is likely to affect the overall risk. However, the effectiveness of such exercises are likely to be limited without direct advice for risk managers in relation to limitations in approaches or other constraints, including practical advice on the likelihood for successful implementation.

Optimization of sanitary measures that achieve an appropriate level of protection (ALOP) as determined by appropriate stakeholder groups will usually involve extensive interactions with risk assessors on issues of public health. It must be emphasized that the role of the risk assessors is primarily to determine the actual public health impact of particular sanitary measures applied to ensure food safety, rather than evaluating "other legitimate factors." These interactions are likely to be iterative and involve a series of two-way communications between assessors and managers.

Consideration of legitimate factors other than public health e.g. economic and social concerns will also enter the process of risk management. In most cases, the risk management process used to arrive at a decision on an appropriate level of protection and appropriate sanitary measures will be broad based, and relevant other legitimate factors will ideally have been identified before that part of risk management begins.

The degree of interaction will depend on a number of factors including:

- The scope and reason for the risk assessment.

For example, if the risk management process has been initiated to identify appropriate sanitary measures to prevent, control, or eliminate an emerging food safety hazard, the risk manager may ask the risk assessor to evaluate the impact of a number of different sanitary measures or combinations of measures on the risk estimate.

As a further example, if the risk management process was initiated to compare alternative sanitary measures in terms of their ability to achieve an appropriate level of protection (ALOP) i.e. an equivalence case, the risk assessor will already have met the needs of the risk manager because the alternative sanitary measure will have been identified when commissioning the risk assessment.

- The judgement of an appropriate level of protection

The risk estimate generated by the risk assessment process may fall outside the range of acceptability or tolerability as determined by the appropriate stakeholders. In such cases, the risk manager may impose stringent sanitary measures e.g. Ban the food or may interact with the risk

assessor to identify sanitary measures that have the potential to significantly reduce an intolerable risk to one that falls within a range of acceptability or tolerability.

- Consideration of "other legitimate factors"

Risk assessors may be involved in interactions between risk managers and other stakeholders in considering the impact of other legitimate factors such as economic concerns and technical feasibility on the choice of ALOP and sanitary measures. For example, risk assessors may be asked to carry out a parallel cost benefit analysis when evaluating the effect of different options for sanitary measures

6.3. Final management decision

Risk managers in consultation with stakeholders make final decisions on measures for the reduction of risk. Risk managers may need to discuss the technical feasibility and practicality of the sanitary measures chosen with stakeholders. Interaction between risk assessors and risk managers is unlikely at this step.

In most cases risk management decisions take the form of a set of sanitary measures that collectively make up the food control system. If an FSO is established, the food control system should include microbiological performance and/or process criteria that are validated as achieving, or contributing to the achievement, of the FSO.

Interaction with risk assessors is not essential to implement a food control system designed on the basis of quantitative risk assessment. However, information gained in the risk assessment process may be useful in validating the effectiveness of the food control system in preventing, eliminating or reducing hazards.

Microbiological criteria are commonly developed as a means of determining the acceptability of a production lot. If an FSO is available the risk managers may require the risk assessor to elaborate a microbiological criterion (step in process, number of samples, methodology, and level of hazards) that is risk based.

7. IMPLEMENTATION OF MANAGEMENT DECISION

Interaction between risk managers and risk assessors is considered unlikely at this step.

8. MONITORING AND REVIEW

8.1. Assessment of effectiveness of measures taken

An essential part of risk management is gathering and analyzing data from a range of points in the food chain so as to ensure that food safety goals are being achieved on an ongoing basis. Some examples include the following:

- Prevalence of a pathogen in herds of animals or flocks of birds.
- Pathogen prevalence at the beginning and end of processing.
- Pathogen prevalence in a food commodity at retail.

8.2. Review risk management and/or assessment as necessary

Emergence of new problems, unsatisfactory epidemiological findings or high variability in compliance with required performance/process criteria might all indicate that the risk assessment process should be revisited. Risk managers may request the re-evaluation of specific inputs to the risk assessment model, or may commission a new risk assessment. Both of these requests will involve interaction between risk managers and risk assessors in formulating the statement of the problem.

9. RECOMMENDATIONS

THE CONSULTATION RECOMMENDED THAT

Food Safety Authorities in Member Countries should structure their food safety system(s) on a risk-based approach that includes appropriate communication and interaction between risk assessors, risk managers, and stakeholders.

FAO and WHO should actively seek opportunities to promote collaborative international risk assessment and risk management activities among Member Countries.

FAO and WHO should encourage the implementation of relevant studies to obtain new and needed information required to support international risk assessment and risk management activities in the area of food safety. This may be best achieved through the FAO and/or WHO collaborative centers, and would involve establishing protocols, providing training, and design of appropriate sampling plans for investigating food-borne risks to human health.

FAO and WHO should emphasize that communication has to occur frequently and iteratively while striving to ensure scientific integrity and achieve freedom from bias in risk assessments.

FAO and WHO should invite the CCFH to take account of the output from this consultation in its work to develop "Principles and Guidelines for the Conduct of Microbiological Risk Management"

FAO and WHO should give strong consideration to how experts in risk management procedures can interact with risk assessors involved in the ad hoc FAO/WHO Consultation on Microbiological Risk Assessment. This interaction is particularly important when deciding on the scope of a particular risk assessment, developing risk assessment policy appropriate to that risk assessment, and ensuring the results of the risk assessment are of maximum utility for risk management.

FAO/WHO and national authorities should consider carefully the training needs of risk assessors and managers so that they are able to undertake the full range of their responsibilities efficiently and effectively.

FAO and WHO should facilitate discussions of the nature and value of food safety objectives especially in the microbiological field. In the light of the report of the Director General of the WHO (EB 105/10 para 10), WHO is requested to expedite consideration of this matter in coordination with FAO.

National governments should acknowledge the importance of functional separation between risk assessment and risk management while ensuring transparent and appropriate interaction between them.

10. REFERENCES

1. *Report of the twenty-second Session*, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Geneva, 23-28 June 1997. ALINORM 97/37 (para. 164).

2. *The Results of the Uruguay Round of Multilateral Trade Negotiations*: The Legal Texts, World Trade Organization, GATT, 1994 (ISBN 92-870-1121-4).

3. *The Application of Risk Analysis to Food Standards Issues.* Report of a Joint FAO/WHO Expert Consultation, World Health Organization, Geneva, Switzerland. 1995.

4. *Risk Management and Food Safety.* Report of a Joint FAO/WHO Expert Consultation, Rome, Italy, 1997. FAO Food and Nutrition Paper, N°65.

5. *The Application of Risk Communication to Food Standards and Safety Matters.* Report of a Joint FAO/WHO Expert Consultation, Rome, Italy, 1998. FAO Food and Nutrition Paper N°70.

6. *Principles and Guidelines for the Conduct of Microbiological Risk Assessment*. Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, (CAC/GL 30 - 1999).

7. *Risk Analysis: 1) Working Principles for Risk Analysis*, Joint FAO/WHO Food Standards Programme, Codex Committee on General Principles. (CX/GP 00/3).

8. *Codex Alimentarius Commission Procedural Manual*, Joint FAO/WHO Food Standards Programme, Eleventh edition, 2000.

9. *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management* at step 3, Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene, July 2000 (CX/FH 00/6).

10. *Principles for the Establishment of Microbiological Rood Safety Objectives and Related Control Measures*. International Commission on Microbiological Specifications for Foods. Food Control 6. 1998, 379-384.

11. *Egg Safety, From Production to Consumption: An Action Plan to Eliminate Salmonella Enteritidis Illness Due to Eggs*, December 10, 1999. President's Council on Food Safety, USA, http://www.foodsafety.gov/~fsg/ceggs.html

12. Experience from non-food risk management. Philippe Hubert. A background paper presented at this Consultation.

11. GLOSSARY OF CODEX TERMS

Risk Assessment is defined in the Codex "Principles and Guidelines for the Conduct of Microbiological Risk Assessment" as a scientifically based process consisting of the following steps: i) hazard identification, ii) hazard characterization, iii) exposure assessment, and iv) risk characterization.

Risk communication is defined in the Codex as: the interactive exchange of information and opinions throughout the risk analysis process concerning risk-related factors and risk perceptions, among assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

Risk management is defined in the Codex as: the process, distinct from risk assessment, of weighing policy alternative in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

12. ANNEX 1 – BACKGROUND PAPERS

A number of working papers were presented over the course of the Consultation. These served as the basis for the discussions, which led to the development of the report and recommendations. The titles of the working papers and author information are listed in this Annex. Some of the working papers may be published in the scientific literature. All inquiries should be directed to the contacts listed below.

Title	Authors	Contact
Hierarchy of process for risk management and risk assessment	Jean-Louis Jouve	Risk Evaluation Unit Principle Administrator – DG XXIV Rue de la Loi 200, B-1049, Brussels, Belgium
Risk assessment of microbiological hazards: scientific advice and foodborne microbiological risk management, Opening address in 32nd CCFH meeting	Jean-Louis Jouve	Same as above
Risk assessment of *Campylobacter jejuni* in poultry	Anna Lammerding	Chief, Risk Assessment-Microbial Food Safety, Health Protection Branch, Health Canada, 110 Stone Road West, Guelph, Ontario N1G 3W4, Canada
How to obtain and evaluate data and opinions of interested parties in risk management	Martin Frid	Consumers International c/o Konsument-Forum Kvarngatan 8 S-283 35 Osby, Sweden
Experience from non-food risk management	Philippe Hubert	Institut de Protection et de Sureté Nucléaire Département Protection de la Santé de l'Homme et Dosimétrie Service d'Evaluation et de Gestion des Risques, BP 6 F- 92265 – FONTENAY AUX ROSES Cedex
Risk perception beyond the psychometric paradigm	Peter M. Wiedemann	Holger Schütz, Peter M. Wiedemann, Philip C.R. Gray Programme Group Humans, Environment and Technology (MUT), 52425 Juelich, Germany
Management of the risk from *Salmonella* Enteritidis in eggs	Kaye Wachsmuth	Deputy Administrator, USDA-FSIS-Office of Public Health and Science Washington, DC 20250-3700 USA

Crisis risk management – Japan's experience with *E. coli* O157:H7	Shigeki Yamamoto	Head – Section of Milk and Meat Hygiene Dept. of Veterinary Public Health National Institute of Public Health, Ministry of Health and Welfare 4-6-1, Shirokanedai, Minato-ku, Tokyo, 108-8638, Japan
Valuation of Health Outcomes in a Regulatory Context	Arie Havelaar	Microbiological Laboratory for Health Protection, WHO Collaborating Centre for Food Safety National Institute of Public Health and the Environment P.O. Box 1, NL-3720 BA Bilthoven
A public health basis for Food Safety Objectives	Arie Havelaar	Same as above
Establishment of appropriate levels of protection (ALOP) according to the SPS agreement	Robert L. Buchanan	Senior Science Advisor US Food and Drug Administration Center for Food Safety and Applied Nutrition, 200 C Street, SW, Washington, DC 20204, USA
Establishment of appropriate levels of protection (ALOP) – the New Zealand experience	Steve Hathaway	Director Programme Development MAF Food Assurance Authority P.O. Box 646 Gisborne, New Zealand
Principles for the Establishment of Microbiological Food Safety Objectives and Related Control Measures	Michiel van Schothorst	Secretary ICMSF c/o Nestlé S.A., Avenue Nestlé 55 CH 1800 Vevey

13. ANNEX 2 - PARTICIPANTS

EXPERTS

Lahsen Ababouch, King Hassan II Institute of Agronomy and Veterinary Medicine, P.O. Box 6202, Rabat, Morocco

Hans Dieter Böhm, Bundesministerium fur Gesundheit Am Probsthof 78a, 53121 Bonn, Germany

Juliane Bräunig, Bundesinstitut fur gesundheitlichen Verbraucherschutz, Und Veterinärmedizin (BgVV), Diedersdorfer Weg 1, 12277 Berlin, Germany

Robert Buchanan, Senior Science Advisor, US Food and Drug Administration, Center for Food Safety and Applied Nutrition, 200 C Street, SW, Washington, DC 20204 USA

Martin Frid, Consumers International, c/o Konsument-Forum, Kvarngatan 8, 283 35 Osby, Sweden

Philipp Hammer, Institute for Hygiene and Food Safety, Federal Dairy Research Centre, Hermann-Weigmann-Str. 1, 24103 Kiel, Germany

Jamal Khair Hashim, Food Quality Control Division, Ministry of Health, Malaysia Department of Public Health, 4th Floor, Block E, Office complex, Jalan Dungun, Damansara Heights, 50490 Kuala Lumpur. Malaysia

Steve Hathaway, Director Programme Development, MAF Food Assurance Authority, P.O. Box 646, Gisborne, New Zealand

Arie H. Havelaar, Microbiological Laboratory for Health Protection, WHO Collaborating Centre for Food Safety, National Institute of Public Health and the Environment, P.O. Box 1, NL-3720 BA Bilthoven, the Netherlands

Philippe Hubert, Institut de Protection et de Sureté Nucléaire, Département Protection de la Santé de l'Homme et Dosimétrie, Service d'Evaluation et de Gestion des Risques BP 6, F- 92265 - FONTENAY AUX ROSES Cedex, France

Jean-Louis Jouve, Risk Evaluation Unit, Principle Administrator - DG XXIV, Rue de la Loi 200, B-1049 Brussels, Belgium *(Chairperson)*

Hilde Kruse, Head, Norwegian Zoonosis Center, Senior Researcher, National Veterinary Institute, P.O. Box 8156 Dep., N-0033 Oslo, Norway

Anna Lammerding, Chief, Microbial Food Safety, Risk Assessment Health Protection Branch, Health Canada, 110 Stone Road West, Guelph, Ontario N1G 3W4, Canada *(Rapporteur)*

Chris Pratt, Microbiological Safety Division, Food Standards Agency, PO Box 31037, Room 416, Ergon House Horseferry Road, London SW1P 3WG, UK

Joachim Reichmuth, Institute for Hygiene and Food Safety, Federal Dairy Research Centre, Hermann-Wiegmann-Str. 1, 24103 Kiel, Germany

Jørgen Schlundt, World Health Organization, Coordinator, Food Safety Programme, Department of Protection of the Human Environment, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland

Michiel Van Schothorst, Secretary ICMSF, c/o Nestlé S.A., Avenue Nestlé 55, CH-1800 Vevey, Switzerland

Laila Rabaah Ahmad Suhaim, Assistant Director, Food Quality Control Division, Ministry of Health, Department of Public Health, 4th Floor, Block E, Office complex, Jalan Dungun, Damansara Heights, 50490 Kuala Lumpur, Malaysia

Sirilak Suwanrangsi, Chief, Fish Inspection Centre, Quality Control Division, Department of Fisheries, Kaset-Klang Chatuchak, Paholyothin Road, Bangkok 10900, Thailand

Paul Teufel, Institute for Hygiene and Food Safety, Federal Dairy Research Centre, Hermann-Weigmann-Str.1, 24103 Kiel, Germany

Dulce M Toccheto, Schuch, Lab. Referencia Animal Ministry of Agriculture, Estrada da Ponta Grossa 3036, CEP 91 785330, Porto Alegre/RS, Rio Grande do Sul, Brazil

I. Kaye Wachsmuth, Deputy Administrator, USDA-FSIS-OPHS, Room 341-E Whitten Bldg, Washington, DC 20250-3700, USA

Ekkehard Weise, Federal Institute for Health Protection, of Consumers and Veterinary Medicine, (BgVV), Diedersdorfer Weg 1, 12277 Berlin, Germany

Henrik Wegener, World Health Organization, Animal and Food-Related Public Health Risks, Dept. of Communicable Diseases, 20 Avenue Appia, 1211 Geneva 27, Switzerland

Peter M. Wiedemann, Forschungszentrum Jülich GmbH, Programmgruppe Mensch, Umwelt, Technik (MUT), 52425 Jülich, Germany

Shigeki Yamamoto, Head of Section of Milk and Meat Hygiene, Dept. of Veterinary Public Health, National Institute of Public Health, Ministry of Health and Welfare, 4-6-1, Shirokanedai, Minato-ku, Tokyo, 108-8638, Japan

SECRETARIAT

Allan Hogue, World Health Organization, Food Safety Programme, Department of Protection of the Human Environment, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland

Hajime Toyofuku, World Health Organization, Food Safety Programme, Department of Protection of the Human Environment, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland

Maria de Lourdes Costarrica G., Senior Officer, Food Quality Liaison Group, Food Quality and Standards Service, Food and Nutrition Division, Food and Agriculture Organization of the United Nations (FAO), Viale delle Terme di Caracalla, 00100 Rome, Italy

Yasmine Motarjemi, World Health Organization, Food Safety Programme, Department of Protection of the Human Environment, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland